

MAY 1 8 2001

510(k) Summary
MegaBeam Fiber Optic Laser Delivery System

K010689

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
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Contact Person: Carol Morello, V.M.D.
Date prepared: February 28, 2001

Name of Device and Name/Address of Sponsor

MegaBeam Fiber Optic Laser Delivery System-Non Sterile
Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Laser, Surgical Fiber Optic Delivery System

Predicate Device

MegaBeam Dental Fiber: Fiber Optic Delivery System
Ceralas D 980nm Diode Laser Fiber Optic Accessory

Intended Use

The company's MegaBeam fiber is intended for use as a fiber optic delivery system for Nd:YAG and other compatible surgical laser systems for oral soft tissue applications for which the laser has already been cleared. It is also intended to be used in conjunction with the Ceralas D 980nm Diode Laser for incision, excision, vaporization, ablation, debulking, hemostasis, and coagulation of soft tissue. Can be used contact or non contact.

Technological Characteristics and Substantial Equivalence

Biolitec's MegaBeam Fiber Optic Delivery System consists of a 200um, 320um, 400um, or 600um quartz glass optical fiber which is terminated with an SMA 905 connector at the proximal end. The optical fiber is coated with polyimide and is jacketed with a material to provide flexibility. The fiber is provided non-sterile.

Performance Data

None required.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carol Morello, VMD
Regulatory Affairs
Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Re: K010689
Trade Name: MegaBeam Fiber Optic Laser Delivery System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: March 7, 2001
Received: March 8, 2001

Dear Dr. Morello:

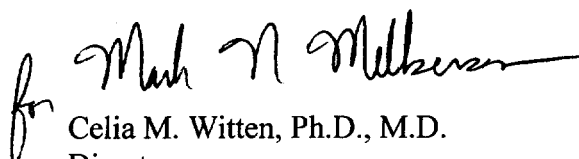
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010689

Device Name: MegaBeam Fiber Optic Delivery System

Indications For Use:

In addition to the already cleared indications:

To be used in conjunction with the Ceralas D 980nm Diode Laser for incision, excision, vaporization, ablation, debulking, hemostasis and coagulation of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N. Melhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010689